Chris W. Cantrell (SBN 290874)
William J. Doyle (SBN 188069)
DOYLE APC
550 West B Street, Fourth Floor
San Diego, CA 92101
Telephone: (619) 736-0000
Facsimile: (619) 736-1111

Attorneys for Plaintiff

UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF CALIFORNIA

ANITA MILLER, Plaintiff, v. ASTORA WOMEN'S HEALTH SYSTEM, LLC, ASTORA WOMEN'S HEALTH, INC, ASTORA WOMEN'S HEALTH HOLDINGS, LLC AMERICAN MEDICAL SYSTEMS, INC, AMERICAN MEDICAL SYSTEMS HOLDINGS, INC, ENDO PHARMACEUTICALS, INC and ENDO HEALTH SOLUTIONS, INC Defendants.	Case No.: 22-cv-01757 COMPLAINT FOR DAMAGES **JURY TRIAL DEMANDED**

PLAINTIFF ANITA MILLER hereby files this Complaint against AMERICAN MEDICAL SYSTEMS, INC., ASTORA WOMEN'S HEALTH, LLC, AMERICAN MEDICAL SYSTEMS HOLDINGS INC., ASTORA WOMEN'S HEALTH, INC., ASTORA WOMEN'S HEALTH HOLDINGS, LLC, ENDO PHARMACEUTICALS, INC., and ENDO HEALTH SOLUTIONS, INC. (collectively referred to as "AMS Defendants" or "AMS") and shows unto the Court as follows:

PARTIES

1. Plaintiff Anita Miller is a 66 year-old resident of the State of California residing in the City of Avery, California. On October 15, 2007, Plaintiff received a Monarc Subfascial Hammock ("Monarc Sling") for the treatment of stress urinary incontinence and a Perigee System with IntePro Mesh ("Perigee System") for the treatment of a cystocele. The surgery was performed at Sonora Regional Medical Center in Sonora, California by Eric Freedman, MD. The Monarc Sling and Perigee System are both Transvaginal Mesh Products manufactured and sold by Defendant American Medical Systems, Inc. In 2021, Plaintiff began to experience significant vaginal pain, dyspareunia and difficulty urinating. Dr. Michael Margolis, a urogynecologist, examined Plaintiff and found that the Monarc Sling had eroded through the vagina and was choking Plaintiff's urethra creating pain and significant urinary problems. Dr. Margolis also found that the mesh had eroded through the anterior vaginal wall and the midline. On August 20, 2021, Plaintiff underwent surgery by Dr. Margolis at El Camino Hospital in Los Gatos, California to excise most of the Monarc Sling. In the Operative Report for this surgery, Dr. Margolis notes, "The sling was found not only to be eroding through the vagina completely, however, was also eroding through the muscularis of the urethra as well causing clearly a near complete transection of the urethra at the mid-level of the urethra." Dr. Margolis also notes that the Monarc Sling had shrunk considerably from its original implant size and had also experienced a significant loss of pore size.

2. Defendant Astora Women's Health, LLC ("ASTORA") is a Delaware limited liability company with its principal place of business located in Eden Prarie,

Minnesota. Astora Women's Health, LLC is the successor in interest to American Medical Systems, Inc.'s women's health division. In 2016, after the FDA reclassified transvaginal mesh products as Class III devices which would require any manufacturer to meet the FDA's most stringent medical device review pathway, Endo Pharmaceuticals, Inc. wound down Astora Women's Health. Pursuant to 10 Del. C. § 3111, ASTORA may be served via its registered agent, Corporation Trust Company, at 1209 N. Orange Street, Wilmington, Delaware 19801.

3. Defendant Astora Women's Health Holdings, LLC ("ASTORA HOLDINGS") is a Delaware limited liability corporation that may be served, pursuant to 10 Del. C. § 3111, through its successor-in-interest ASTORA which may be served via its registered agent, Corporation Trust Company, at 1209 N. Orange Street, Wilmington, Delaware 19801.

4. Defendant American Medical Systems, Inc., ("AMS INC.") was a Delaware Corporation with its principal place of business in Minnesota. In 2011, AMS was acquired by, and became a wholly-owned subsidiary of, Endo Pharmaceuticals, Inc. In December 2014, American Medical Systems, Inc. was converted to American Medical Systems, LLC, a Delaware limited liability company. In September 2015, American Medical Systems, LLC was re-named Astora Women's Health LLC. At all times relevant hereto, AMS designed, manufactured, marketed and sold various medical devices used to treat stress urinary incontinence and pelvic organ prolapse including the Monarc Sling and Perigee Pelvic Floor Repair System at issue in this matter. Pursuant to 10 Del. C. § 3111, AMS may be served through its successor-in-interest ASTORA which may be served via its registered agent, Corporation Trust Company, at 1209 N. Orange Street, Wilmington, Delaware 19801.

5. Defendant American Medical Systems Holdings Inc., ("AMS HOLDINGS") was a Delaware corporation with its principal place of business in Minnetonka, Minnesota. AMS HOLDINGS operated as a holding company and through its subsidiary, American Medical Systems, Inc., manufactured medical devices for the

treatment of stress urinary incontinence and pelvic organ prolapse, including the Monarc Sling and Perigee System at issue here. Pursuant to 10 Del. C. § 3111, AMS HOLDINGS may be served via its registered agent, Corporation Trust Company, at 1209 N. Orange Street, Wilmington, Delaware 19801.

6. Defendant Endo Pharmaceuticals, Inc. ("ENDO") is a Pennsylvania corporation, with its principal place of business at 100 Endo Boulevard, Chadds Ford, Pennsylvania. In 2011, ENDO purchased American Medical Systems, Inc. Pursuant to 10 Del. C. § 3111, ENDO may be served via its registered agent, Corporation Trust Company, at 1209 N. Orange Street, Wilmington, Delaware 19801.

7. Defendant Endo Health Solutions Inc. ("ENDO HEALTH") previously known as Endo Pharmaceuticals Holdings, Inc., is a Delaware corporation with its principal place of business at 100 Endo Boulevard, Chadds Ford, Pennsylvania. ENDO HEALTH is the parent corporation of wholly-owned subsidiaries ENDO, AMS and AMS HOLDINGS. Pursuant to 10 Del. C. § 3111, ENDO HEALTH may be served via its registered agent, Corporation Trust Company, at 1209 N. Orange Street, Wilmington, Delaware 19801.

8. In 2011, Defendant ENDO acquired AMS and AMS HOLDINGS which became wholly-owned subsidiaries of ENDO. As part of this acquisition, ENDO purchased and assumed all liability relating to legal claims arising from the implantation of defective AMS Vaginal Mesh Products, including the Monarc and Perigee. AMS INC., ASTORA, AMS HOLDINGS, ASTORA HOLDINGS, ENDO and ENDO HEALTH shall be referred to collectively as "AMS Defendants" or "AMS."

9. AMS Defendants are vicariously liable for the acts and omissions of their respective employees and/or agents who were at all times acting on AMS's behalf and within the scope of their employment or agency.

10. At all times material hereto, AMS designed, developed, manufactured, marketed, distributed, and sold products to treat pelvic organ prolapsed and/or stress urinary incontinence, including the Monarc Sling and Perigee System that is the subject

of this lawsuit. In 2011, AMS became a wholly owned subsidiary of ENDO and AMS began operating as Astora Women's Health, LLC.

11. At all times alleged herein, AMS included and includes any and all parents, subsidiaries, affiliates, divisions, partners, joint ventures and organization units of any kind, their predecessors, successors, and assigns, and their officers, directors, employees, agents, representatives and any and all other persons acting on their behalf.

JURISDICTION AND VENUE

12. Damages sought in this matter are in excess of $75,000.00. Subject matter jurisdiction is proper pursuant to 28 U.S.C. § 1332.

13. This Court has diversity subject-matter jurisdiction over this action pursuant to 28 U.S.C. § 1332(a), because it is a civil action in which the matter in controversy exceeds the sum or value of $75,000, exclusive of interests and costs, and is between citizens of different States.

14. Venue is proper in this Court pursuant to 28 U.S.C. § 1391(a) and (c), because the Court's subject matter jurisdiction is based upon diversity and a substantial part of the events or omissions giving rise to the claim occurred here. Specifically, the Plaintiff currently resides and resided at all times relevant hereto in this district. Further, Plaintiff's hernia mesh implant surgeries as well as all surgeries to treat complications from the hernia mesh implants occurred in this district.

15. AMS Defendants have conducted and continue to conduct, substantial business in the State of California and in this District; distribute their Vaginal Mesh Products, including the Monarc and Perigee, in this District; receive substantial compensation and profits from sales of these products in this District; and made material omissions and misrepresentations and breaches of warranties in this District, so as to subject them to personal jurisdiction in this District.

16. Each of the Defendants are, or were at all times relevant hereto, registered to transact business in the State of California.

FACTUAL ALLEGATIONS

A. Plaintiff

17. Plaintiff Anita Miller is a 66-year old resident citizen of the State of California who resides in Avery, California. On January 15, 2007, Plaintiff received a Perigee System for the treatment of a cystocele and a Monarc Subfascial Hammock for the treatment of stress urinary incontinence. During the relevant time period, the Perigee System and the Monarc Subfascial Hammock were designed, manufactured, marketed and sold by Defendant American Medical Systems, Inc. The implant surgery was performed by Dr. Eric Freedman at Sonora Regional Medical Center in Sonora, California.

18. In late 2020 or early 2021, Plaintiff began to experience significant pelvic and vaginal pain, urinary retention and other urinary issues. Urogynecologist Michael Margolis, MD examined Plaintiff and found the Monarc Sling had completely eroded through the vagina as well as the urethra thereby obstructing Plaintiff's bladder significantly. Dr. Margolis recommended surgery to remove the Monarc Sling which occurred on August 20, 2021 at El Camino Hospital, Los Gatos, California.

19. Dr. Margolis recorded the following findings in the Operative Report for Plaintiff's August 20, 2021 revision surgery:

(a) "there was extensive scar application in the wound field and medially involving the sling and the sling track. ... The scar tissue was dense and the sling was found to be tightly choking up on the mid urethra ..."

(b) "'The sling was partially occluding the urethra causing the partial bladder outlet obstruction. The sling was carefully and meticulously dissected away from the urethra and measurement of the sling in situ showed the width of the sling to the 0.4 cm, thus confirming that the sling had shrank substantially from its implant width."

(c) "The sling was found not only to be eroding through the vagina completely, however, was also eroding through the muscularis of the urethra as well causing clearly a near complete transection of the urethra at the mid-level of the urethra."

(d) "The sling was found to be covered in a dense scar plating throughout with substantial bridging fibrosis and loss of pore size."

(e) "The sling was tight and bandlike and during its dissection away from the urethra shards of sling broke apart and many of those shards could not be retrieved and were thus left behind."

20. As a result of AMS's Monarc and Perigee implants, Plaintiff suffered significant mental and physical pain and suffering, permanent injury, underwent corrective surgery or surgeries, and suffered financial or economic loss, including, but not limited to, obligations for medical services and expenses. Additionally, these Implants have irrevocably altered her marital relationship as Plaintiff is unable to have a normal marital relationship with her husband due the pain caused by the Implants.

21. The Monarc and Perigee implants, designed, manufactured, marketed, distributed, sold and/or supplied by the AMS Defendants were defectively designed, tested, manufactured and marketed and contained inadequate warnings.

B. Synthetic Mesh for the Treatment of POP and SUI.

22. The Monarc Subfascial Hammock and Perigee System were marketed and sold by The AMS Defendants as safe and efficacious treatments for stress urinary incontinence and pelvic organ prolapse, respectively.

23. Stress urinary incontinence ("SUI") is the involuntary loss of urine during movement that puts pressure on the bladder, such as laughing, coughing, or sneezing, or during aerobic or strenuous exercise. Although incontinence is suffered by men and women, it is more common in women and is typically the result of menopause, or physical changes that occur to the body during pregnancy or childbirth. Stress urinary incontinence can be embarrassing and uncomfortable.

24. Pelvic organ prolapse ("POP") is a weakening of the vaginal muscle and tissues such that the vaginal organs can no longer be adequately supported and one or more of the vaginal organs drops. Childbirth is the most common cause of pelvic organ prolapse in women. The bladder, uterus or rectum are the most common prolapsed

vaginal organs. Pelvic organ prolapse is uncomfortable and can interfere with urinary and defecatory functions, many daily activities, and sex. For example, a prolapsed bladder can prevent the muscles that ordinarily force the urethra shut from squeezing as tightly as they should, resulting in an involuntary loss of urine.

25. Both SUI and POP are common conditions experienced by women and among the most prevalent urological surgeries in the US. It is estimated that over $12 billion is spent annually in the treatment of stress urinary incontinence in women.

26. Both SUI and POP are, in most cases, treatable. A woman who elects to have her SUI or POP surgically treated has several options. SUI, for example, can be corrected through traditional abdominal surgery using sutures to attach the urethra to a ligament in the pelvis (known as the "Burch procedure"). SUI can also be surgically addressed using synthetic materials such as suprapubic mid-urethral "slings" placed under the urethra to provide support. In essence, each end of a long, thin piece of polypropylene mesh (approximately 9 x 1 cm) is affixed to both sides of the groin or the pubic bone. The mid-part of the sling is placed under the mid-urethra where it provides support for the urethra which allows the bladder neck and urethra to better resist presume. The sling acts as a hammock of sorts to support the urethra. Similarly, meshes were used to treat prolapsed or falling pelvic organs by acting in a similar manner. The sheet of mesh is anchored and placed under the prolapsing organ to support it. The meshes used to treat POP can be synthetic, composite or biologic and can be implanted via the abdominal route or transvaginal route. The vast majority of slings and POP meshes are constructed of polypropylene. Polypropylene mesh products are comprised of interwoven threats of the thermoplastic polymer, polypropylene. Polypropylene is a cheap plastic polymer used to manufacture all types of plastic items from fishing line to plastic chairs.

27. In the 1990s, gynecologists began using surgical mesh designed for the repair of hernias, in the treatment of POP and SUI. Manufacturers, including AMS, began to modify the mesh used in hernia repair to be used as products specifically intended to

correct POP and/or SUI. AMS sold pelvic mesh"kits" which can include not only the surgical mesh, but also tissue fixation anchors and insertion tools.

28. At all times relevant hereto, the Vaginal Mesh Products manufactured by AMS were considered Class II medical devices. AMS sought and obtained FDA clearance (not FDA approval) to place onto the market both the Perigee System and the Monarc Subfascial Hammock under Section 510(k) of the Medical Device Amendment to the Food, Drug, and Cosmetics Act. Section 510(k) provides for marketing of a medical device if the device is deemed "substantially equivalent" to other predicate devices marketed prior to May 28, 1976. Section 510(k) allowed a manufacturer to bypass some of the rigorous pre-approval testing requirements often required by the FDA for Class III medical devices. No formal review for safety or efficacy is required, and no formalreview for safety or efficacy was ever conducted by the AMS with regard to its polypropylene Vaginal Mesh Products, including the Monarc and Perigee.

29. Under the 510(k) process, a manufacturer must provide a premarket notification that allows the FDA to determine whether the device is substantially equivalent to a "predicate device." A predicate device is one that the FDA has placed into one of three classification categories and "cleared" for marketing.

30. Unlike Class III medical devices, such as an artificial heart or an Automated External Defibrillator, Class II devices do not require "approval" by the FDA. Whereas Class III devices cannot be sold until the manufacturer demonstrates to the FDA, through adequate and well-controlled clinical trials, that the proposed device is safe and effective, there is no such requirement for Class II devices. The "premarket notification" process -- for Class II devices – is not focused on whether the device is safe and effective, but rather is concerned with whether the proposed device is substantially equivalent to an existing predicate device that was already cleared for marketing by the FDA. Many of AMS's Vaginal Mesh Products, including the Perigee and Monarc Sling, were introduced via the 510(k) process using a vaginal mesh product called "ProteGen" as either the direct or indirect predicate device. ProteGen was the first vaginal mesh product introduced

onto the market and was withdrawn shortly after its introduction after the FDA found FDA further stated, "[u]se of ProteGen in the treatment of female urinary incontinence is associated with higher than expected rate of vaginal erosion and dehiscence, and does not appear to function as intended."

31. By utilizing the 510(k) process, AMS was, in many cases, able to introduce its vaginal mesh products, including the Monarc and Perigee, onto the market with little or no pre-market testing to ensure efficacy and safety.

32. At the request of the FDA in 2012, the National Institute of Health (NIH) conducted a thorough review of the 510(k) process, reaching the following major conclusion:

> **The 510(k) clearance process is not intended to evaluate the safety and effectiveness of medical devices with some exceptions. The 510(k) process cannot be transformed into a pre-market evaluation of safety and effectiveness so long as the standard for clearance is substantial equivalence to any previously cleared device.**

33. The NIH explained: "The assessment of substantial equivalence does not require an independent demonstration that the new device provides a 'reasonable assurance of safety and effectiveness.'" Further, the NIH even pointed out that the classification of predicate devices approved for sale prior to 1976 "did not include any evaluation of the safety and effectiveness of individual medical devices . . .Thus it is common for devices to be cleared through the 510(k) program by being found substantially equivalent to devices that were never individually evaluated for safety and effectiveness, either through the original device classification program or through the 510(k) process."

34. As the NIH noted, the use of devices that were never evaluated for safety and efficacy as predicate devices gives no assurances of safety and efficacy for the applicant 510(k) device. However, The AMS Defendants and other pelvic mesh manufacturers, further exploited the 510(k) process by using mesh implants that were

eventually removed from the market due to safety and efficacy problems as the predicate devices to get 510(k) clearance.

35. The AMS's Vaginal Mesh Products, including the Monarc and Perigee, contain monofilament polypropylene mesh. AMS designed the Monarc Sling and Perigee System to be permanently implanted into the recipient's body. Despite claims that polypropylene is inert, the scientific evidence shows that this material, as implanted in Plaintiff, is biologically incompatible with human tissue and promotes anegative immune response in a large subset of the population implanted with polypropylene Vaginal Mesh Products, including the Monarc at issue herein. This negative response promotes inflammation of the pelvic tissue and can contribute to the formation of severe adverse reactions to the mesh. When this mesh is inserted according to the manufacturers' instructions, it creates a non-anatomic condition in the pelvis leading to chronic pain and functional disabilities.

36. This "host defense response" by a woman's pelvic tissues promotes degradation of the polypropylene mesh and the pelvic tissue, and causes chronic inflammation of the pelvic tissue, shrinkage or contraction of the mesh leading to nerve entrapment, further inflammation, chronic infectious response, and chronic pain. It also can cause new-onset painful sexual relations, significant urinary dysfunction, vaginal shortening and anatomic deformation, and can contribute to the formation of severe adverse reactions to the mesh. AMS was aware, or should have been aware, of these serious complications associated with their Monarc and Perigee including the frequency and permanence of these complications.

37. Synthetic materials like polypropylene, including that used by AMS in the Monarc and Perigee, are known to induce an acute inflammatory response, followed by chronic inflammatory response and foreign-body reaction. A chronic inflammatory response and heightened foreign body reaction have the potential to result in failure of the device to perform safely and effectively, with significant adverse consequences for the

patient. Further, a prolonged inflammatory response exposes the polypropylene mesh to a continuous bath of oxidants that causes degradation of the mesh.

38. The polypropylene mesh used by AMS for the Monarc and Perigee, contracts or shrinks after implantation as a result of the development of scar tissue exacerbated by the foreign body reaction. Polypropylene mesh is known to shrink by up to over 50% during healing. When transvaginal mesh shrinks during the normal healing process this can lead to traction on adjacent structures including muscles and nerves, causing muscle and nerve pain.

39. On October 20, 2008, the Food and Drug Administration ("FDA") issued a Public Health Notification that described over 1,000 reports of complications (otherwise known as "adverse events") that had been reported over a three year period relating to transvaginal mesh products. Although the FDA notice did not identify the transvaginal mesh manufacturers by name, a review of the FDA's MAUDE database indicates that the Defendant is one of the manufacturers of the products that are the subject of the notification. In 2008, the FDA described the complications associated with these transvaginal mesh products as "**rare**."

40. On July 13, 2011, the FDA issued a Safety Communication wherein the FDA stated that "serious complications associated with surgical mesh for transvaginal repair of POP are not rare" (emphasis in the original).

41. The FDA Safety Communication also stated, "Mesh contraction (shrinkage) is a *previously unidentified risk* of transvaginal POP repair with mesh that has been reported in the published scientific literature and in adverse event reports to the FDA . . . Reports in the literature associate mesh contraction with vaginal shortening, vaginal tightening and vaginal pain." (emphasis in original).

42. September 2011, the FDA acknowledged the need for additional data and noted in "Surgical Mesh For Treatment of Women with Pelvic Organ Prolapse and Stress Urinary Incontinence" that the literature and information developing on SUI repair with mesh "indicates that serious complications can occur…[and] a case can be made for

additional premarket and/or post market studies to better address the risk/benefit of all mesh products used for SUI."

43. In the Safety Communication, the FDA concluded that "a mesh procedure may put the patient at risk for requiring additional surgery or for the development new complications. Removal of the mesh due to mesh complications may involve multiple surgeries and significantly impair the patient's quality of life. Complete removal of mesh may not be possible."

44. After the 2011 FDA notification that mesh complications from POP repairs were "not rare," a 2013 article was published that stated: "as outlined in the FDA notifications, patient should be forewarned that some transvaginal mesh complications are life altering and might not always be surgically correctable. Furthermore, that study noted that "the women who received both MUS (Mid-urethral Sling) and TM (transvaginal mesh) represented a complicated surgical group. Fifteen women (43%) required MUS takedown concurrently with prolapse mesh excision. Two-thirds of these women had associated chronic pelvic pain and vaginal pain, in addition to their urinary symptoms."

45. On January 3, 2012, the FDA ordered the manufacturers of transvaginal mesh devices for the treatment of pelvic organ prolapse to complete post-market surveillance studies, commonly referred to as "522 Studies." Instead of completing these 522 Studies to evaluate the safety and efficacy of their products, AMS decided to withdraw all of their transvaginal mesh products for the treatment of Pelvic Organ Prolapse, including the Perigee System, from the market. With the exception of Coloplast Corp. ("Coloplast") and Boston Scientific Corp. ("BSC"), all other manufacturers of transvaginal mesh implants for the treatment of POP withdrew their products from the market rather than undergo the FDA ordered "522 Studies." And Coloplast and BSC withdrew all of their transvaginal POP mesh products with the exception of three products (the Restorelle DirectFix Anterior, Uphold LITE Vaginal Support System and Xenform Soft Tissue Repair System).

46. On March 27, 2013 the FDA updated the Urogynecologic Surgical Mesh Implant website to include more information for patients about stress urinary incontinence (SUI). This update provides the FDA's current thinking about the use of surgical mesh for repair of SUI and is based on an analysis of adverse events reported to the FDA, findings reported in the scientific literature and input received from the Sept. 9, 2011 meeting of the Obstetrics and Gynecology Devices Panel of the Medical Device Advisory Committee.

47. On April 29, 2014, the FDA proposed to reclassify surgical for transvaginal repair of POP from class II to III and require premarket approval (PMA) applications for these devices. This would require manufacturers to provide clinical data in a PMA application to support the safety and effectiveness of surgical mesh for transvaginal POP. Both of these proposed rule changes were finalized by the FDA on January 5, 2016.

48. On April 16, 2019, the FDA ordered Coloplast and BSC to stop selling and distributing their Restorelle DirectFix Anterior, Uphold LITE Vaginal Support System and Xenform Soft Tissue Repair System after concluding the Premarket Approval Applications for these products "did not provide reasonable assurances of safety and effectiveness." After the FDA's removal of these products, no more transvaginal mesh products for the treatment of POP remained on the market in the United States.

49. At the time AMS began marketing the Monarc and Perigee, AMS were aware the Monarc and Perigee were associated with each and every one of the adverse events communicated by the FDA in its July 13, 2011 Safety Communication.

50. AMS knew or should have known that the Monarc and Perigee unreasonably exposed patients to the risk of serious harm while conferring no benefit over available feasible alternatives that do not involve the same risks. The AMS Defendants were also aware that:

(a) Some of the predicate devices for the Monarc and Perigee products had high failure and complication rates;

(b) There were and are significant differences between the Monarc and Perigee products and some or all of the predicate devices, rendering

them unsuitable for designation as predicate devices;

(c) These significant differences render the disclosures to the FDA incomplete and misleading; and

(d) The Monarc and Perigee products were and are causing numerous patients' severe injuries and complications.

51. AMS failed to perform adequate testing and research to determine and evaluate the risks and benefits of the Monarc and Perigee products. AMS continued to promote the Monarc and Perigee as safe and effective even when no clinical trials had been done supporting the products' safety or efficacy.

52. While AMS would train doctors how to implant their Vaginal Mesh Products, including the Monarc and Perigee, they failed to train doctors how to treat complications or remove these mesh implants should it be necessary. AMS also failed to design and establish a safe, effective procedure for removal of their Vaginal Mesh Products; thus, in the event of a failure, injury, or complications, it is impossible to easily and safely remove these products.

53. The scientific evidence shows that the material from which the Perigee and Monarc are made is biologically incompatible with human tissue and promotes a negative immune response in a large subset of the population implanted with the Monarc and Perigee, including the Plaintiff Miller. This negative response promotes inflammation of the vaginal tissue and contributes to the formation of severe adverse reactions to the mesh, such as those experienced by Plaintiff.

54. The FDA defines both "degradation" and "fragmentation" as "device problems" to which the FDA assigns a specific "device problem code." "Material fragmentation" is defined as an "[i]ssue associated with small pieces of the device breaking off unexpectedly" and "degraded" as an "[i]ssue associated with a deleterious change in the chemical structure, physical properties, or appearance in the materials that are used in device construction." The Monarc and Perigee were unreasonably susceptible to degradation and fragmentation inside the body.

55. The Monarc and Perigee were unreasonably susceptible to shrinkage and contraction inside the body. Additionally, the Monarc and Perigee were susceptible to the gradual elongation and deformation of the mesh when it is placed under tension inside the body.

56. The Monarc and Perigee were marketed to the medical community and to patients as safe, effective, reliable, medical devices, implanted by safe and effective, minimally invasive surgical techniques, and as safer and more effective as compared to available feasible alternative treatments of pelvic organ prolapse and stress urinary incontinence, and other competing products.

57. AMS omitted the risks, dangers, defects, and disadvantages of the Monarc and Perigee, and advertised, promoted, marketed, sold and distributed the Monarc and Perigee as safe medical devices when AMS knew or should have known that the Monarc and Perigee were not safe for their intended purposes, and that the Monarc and Perigee would cause, and did cause, serious medical problems in some patients, including the Plaintiff.

58. Contrary to AMS's representations and marketing to the medical community and to the patients themselves, the Monarc and Perigee have high rates of failure, injury, and complications, fail to perform as intended, require frequent and often debilitating re-operations, and have caused severe and irreversible injuries, conditions, and damage to a significant number of women, including the Plaintiff, making them defective under the law.

59. The specific nature of the Monarc and Perigee's defects include, but is not limited to, the following:

(a) The use of polypropylene and collagen material in the Monarc and Perigee and the immune reactions that result from such material, causing adverse reactions and injuries;

(b) The design of the Monarc and Perigee to be inserted transvaginally, into and through an area of the body with high levels of bacteria that

can adhere to the mesh causing immune reactions and subsequent tissue breakdown and adverse reactions and injuries;

(c) Biomechanical issues with the design of the Monarc and Perigee, including, but not limited to, the propensity of the Monarc and Perigee to contract or shrink inside the body, that in turn cause surrounding tissue to be inflamed, become fibrotic, and contract, resultingin injury;

(d) The use and design of arms and anchors in the Monarc and Perigee, which, when placed in the women, are likely to pass through contaminated spaces and that can injure major nerve routes in the pelvic region;

(e) The propensity of the Monarc and Perigee to "creep," or to gradually elongate and deform when subject to prolonged tension inside the body;

(f) The inelasticity of the Monarc and Perigee, causing them to be improperly mated to thedelicate and sensitive areas of the vagina and pelvis where they are implanted, and causing pain upon normal daily activities that involve movement in the pelvic region (e.g., intercourse, defecation, walking);

(g) The propensity of the Monarc and Perigee for degradation or fragmentation over time, which causes a chronic inflammatory and fibrotic reaction, and results in continuing injury over time;

(h) The creation of a non-anatomic condition in the pelvis leading to chronic pain and functional disabilities when the mesh is implanted according to the manufacturers' instructions;

(i) The procedure itself, which is part of AMS's Monarc and Perigee products, requires the physician to insert the device "blindly" resulting in nerve damage and damage to other internal organs; and

(j) The design of trocars, which are part of the Monarc and Perigee devices and are used to insert the implants into the vagina, are defective because the device requires tissue penetration in nerve rich environments which results frequently in the destruction of nerve endings causing pain and other injuries.

60. The Monarc and Perigee are also defective due to AMS's failure to adequately warn or instruct the Plaintiff and/or her health care providers of subjects including, but not limited to, the following:

(a) The Monarc and Perigee's propensities to contract, retract, and/or shrink inside the body;

(b) The Monarc and Perigee's propensities for degradation, fragmentation and/or creep;

(c) The Monarc and Perigee's inelasticity preventing proper mating with the pelvic floor and vaginal region;

(d) The rate and manner of mesh erosion or extrusion;

(e) The risk of chronic inflammation resulting from the Monarc and Perigee;

(f) The risk of chronic infections resulting from the Monarc and Perigee;

(g) The risk of permanent vaginal or pelvic scarring as a result of the Monarc and Perigee;

(h) The Monarc and Perigee's propensities to contract, retract, and/or shrink inside the body;

(i) The Monarc and Perigee's propensities for degradation, fragmentation and/or creep;

(j) The Monarc and Perigee's propensities to contract, retract, and/or shrink inside the body;

(k) The Monarc and Perigee's propensities for degradation, fragmentation and/or creep;

(l) The Monarc and Perigee's inelasticity preventing proper mating with the pelvic floor and vaginal region;

(m) The rate and manner of mesh erosion or extrusion;

(n) The risk of chronic inflammation resulting from the Monarc and Perigee;

(o) The risk of chronic infections resulting from the Monarc and Perigee;

(p) The risk of permanent vaginal or pelvic scarring as a result of the Monarc and Perigee;

(q) The risk of permanent vaginal shortening resulting from the Monarc and Perigee;

(r) The risk of recurrent, intractable pelvic pain and other pain resulting from the Monarc and Perigee;

(s) The need for corrective or revision surgery to adjust or remove the Monarc and Perigee;

(t) The severity of complications that could arise as a result of implantation of the Monarc and Perigee;

(u) Treatment of pelvic organ prolapse and stress urinary incontinence with the Monarc and Perigee is no more effective than feasible available alternatives;

(v) Treatment of pelvic organ prolapse and stress urinary incontinence with the Monarc and Perigee exposes patients to greater risk than feasible available alternatives;

(w) Treatment of pelvic organ prolapse and stress urinary incontinence with the Monarc and Perigee makes future surgical repair more difficult than feasible available alternatives;

(x) Use of the Monarc and Perigee puts the patient at greater risk of requiring additional surgery than feasible available alternatives;

(w) Treatment of pelvic organ prolapse and stress urinary incontinence with the Monarc and Perigee makes future surgical repair more difficult than feasible available alternatives;

(x) Use of the Monarc and Perigee puts the patient at greater risk of requiring additional surgery than feasible available alternatives;

(y) Removal of the Monarc and Perigee due to complications may involve multiple surgeries and may significantly impair the patient's quality of life; and

(z) Complete removal of the Monarc and Perigee may not be possible and may not result in complete resolution of the complications, including pain.

61. AMS have underreported information about the propensity of the Monarc and Perigee to fail and cause injury and complications, and have made false representations regarding the efficacy and safety of the Monarc and Perigee through various means and media. AMS have also underreported information about the injuries caused by the use of the implantation kits and surgical technique instructions that accompany their pelvic meshes.

62. At all times material hereto, feasible and suitable alternatives to the Monarc and Perigee have existed that do not present the same risks, in both frequency and severity, as the Monarc and Perigee.

63. The Monarc and Perigee were at all times utilized and implanted in a manner foreseeable to the AMS Defendants, as they generated the instructions for use, created the procedures for implanting the devices, provided the surgical kits for implantation, and provided training for the implanting physician.

64. The AMS Defendants provided incomplete and insufficient training and information to physicians regarding the use of the Monarc and Perigee and the aftercare of patients implanted with these products. This was done in order to increase the number of physicians utilizing the Monarc and Perigee, and thus increase the sales of these products, and also leading to the dissemination of inadequate and misleading information to patients, including Plaintiff.

65. The Monarc and Perigee implanted in the Plaintiff were in the same or substantially similar condition as they were when they left AMS's possession, and in the condition directed by and expected by the AMS Defendants.

66. Plaintiff and her physicians foreseeably used and implanted the Monarc and Perigee, and did not alter them in an unforeseeable manner.

67. The injuries, conditions, and complications suffered by numerous women around the world who have been implanted with the Monarc and Perigee include, but are not limited to, erosion, mesh contraction, infection of the mesh, fistula, inflammation, scar tissue, organ perforation, dyspareunia (pain during sexual intercourse), blood loss,

neuropathic and other acute and chronic nerve damage and pain, pudendal nerve damage, pelvic floor damage, chronic pelvic pain and other debilitating complications.

68. In many cases women, including the Plaintiff, have been forced to undergo extensive medical treatment, including, but not limited to, surgery to locate and remove mesh, surgery to repair pelvic organs, tissue and/or nerve damage, the use of pain control and other medications, injections into various areas of the pelvis, spine and the vagina.

69. The medical and scientific literature studying the effects of Vaginal Mesh Products, including the Monarc and Perigee products, have examined each of these injuries, conditions, and complications, and has reported that they are causally related to these implants.

70. The AMS Defendants misrepresented and/or misled to the medical community, Plaintiff and the public that the Monarc and Perigee had been tested and were found to be safe and effective for the purposes of treating incontinence and/or prolapse.

71. These representations were made by the AMS Defendants with the intent of inducing the medical community, Plaintiff, and the public, to recommend, prescribe, dispense, and purchase the Monarc and Perigee for use as a means of treatment for stress urinary incontinence and/or pelvic organ prolapse, all of which evinced an indifference to the health, safety, and welfare of Plaintiff.

72. In representations to Plaintiff and/or to Plaintiff's healthcare providers, the AMS Defendants concealed and intentionally omitted the following material information:

(a) That the Monarc and Perigee were not as safe as other products and procedures available to treat incontinence and/or prolapse;

(b) That the risk of adverse events with the Monarc and Perigee was higher than with other products and procedures available to treat incontinence and/or prolapse;

(c) That the risk of adverse events with the Monarc and Perigee were not adequately tested and were known by Defendants;

(d) That the limited clinical testing revealed the Monarc and Perigee had a higher risk of adverse effects, in addition to, and above and beyond

those associated with other products and procedures available to treat incontinence and/or prolapse;

(e) That AMS Defendants failed to follow up on the adverse results from clinical studies and buried and/or misrepresented those findings;

(f) That AMS Defendants was aware of dangers in the Monarc and Perigee in addition to and above and beyond those associated with other products and procedures available to treat incontinence and/or prolapse;

(g) That the Monarc and Perigee were dangerous and caused adverse side effects, including but not limited to higher incidence of erosion and failure, at a much more significant rate than other products and procedures available to treat incontinence and/or prolapse;

(h) That patients needed to be monitored more regularly than usual while using the Monarc and Perigee and that in the event the Monarc and Perigee needed to be removed that the procedures to remove them had a very high failure rate and/or needed to be performed repeatedly; and

(i) Removal of contracted, eroded and/or infected mesh can require multiple surgical interventions for removal of mesh and results in scarring on fragile compromised pelvic tissue and muscles.

73. AMS Defendants had sole access to material facts concerning the defective nature of the Monarc and Perigee and their propensity to cause serious and dangerous side effects and hence, cause dangerous injuries and damage to persons who used the Monarc and Perigee.

74. AMS's concealment and omissions of material fact concerning the safety of the Monarc and Perigee were made to cause Plaintiff's physicians and healthcare providers to purchase, prescribe, and/or dispense the Monarc and Perigee; and/or to mislead Plaintiff into using the Monarc and Perigee.

75. At the time Plaintiff received the Monarc and Perigee implants, she was unaware of the falsehood of these representations, and reasonably believed them to be true.

76. AMS Defendants knew and had reason to know that the Monarc and Perigee could and would cause severe and grievous personal injury to the users of the Monarc and Perigee, and that they were inherently dangerous in a manner that exceeded any purported, inaccurate, or otherwise ineffectual warnings.

77. At all relevant times herein, the AMS Defendants continued to promote the Monarc and Perigee as safe and effective even when no clinical trials had been done supporting long- or short-term efficacy.

78. In doing so, the AMS Defendants failed to disclose the known risks and failed to warn of known or scientifically knowable dangers and risks associated with the Monarc and Perigee.

79. At all relevant times herein, AMS Defendants failed to provide sufficient warnings and instructions that would have put the Plaintiff and the general public on notice of the dangers and adverse effects caused by implantation of the Monarc and Perigee including, but not limited to, mesh erosion, dense adhesions, worsening dyspareunia, chronic pain, infection, sepsis, permanent disfigurement and multiple surgeries for mesh removal.

80. The Monarc and Perigee as designed, manufactured, distributed, sold and/or supplied by the AMS Defendants were defective as marketed due to inadequate warnings, instructions, labeling and/or inadequate testing in the presence of AMS's knowledge of lack of safety.

81. As a result of having the Monarc and Perigee implanted in her, the Plaintiff has experienced significant mental and physical pain and suffering, has sustained permanent injury, has undergone medical treatment and will likely undergo further medical treatment and procedures, has suffered financial or economic loss, including, but not limited to, obligations for medical services and expenses, and/or lost income, and other damages.

82. As a result of the Monarc and Perigee, Plaintiff suffered erosion of the mesh through her vagina and her urethra obstructing her bladder, extensive severe scar tissue and the sling broke into shards that could not be removed. The Monarc sling eroded through the muscularis of the urethra and caused a near complete transection of the urethra. The Monarc sling had also shrank considerably partially occluding the urethra. Additionally, these Implants have irrevocably altered Plaintiff's marital relationship with her husband. Plaintiff is unable to have a normal marital relationship due the pain Plaintiff experiences from the Monarc and Perigee especially during intercourse.

83. The Monarc sling and Perigee were implanted in Plaintiff with the intention of treating the Plaintiff for stress urinary incontinence and pelvic organ prolapse, respectively, uses for which Defendants marketed and sold the Monarc and Perigee.

C. AMS Defendants' Malicious, Oppressive and Fraudulent Acts and Omissions.

84. AMS Defendants sold their Vaginal Mesh Products, including the Monarc and Perigee, to Plaintiff's healthcare providers and other healthcare providers in the state of California and throughout the United States without doing adequate testing to ensure that the Monarc and Perigee were reasonably safe for implantation in the female pelvic area.

85. AMS Defendants sold the Monarc and Perigee to Plaintiff's health care providers and other health care providers in the state of California and throughout the United States in spite of their knowledge that the Monarc and Perigee can shrink, disintegrate and/or degrade inside the body, and cause the other problems heretofore set forth in this complaint, thereby causing severe and debilitating injuries suffered by the Plaintiff.

86. AMS. Defendants ignored reports from patients and health care providers throughout the United States and elsewhere of the failures of the Monarc and Perigee

implants, to perform as intended, which led to the severe and debilitating injuries suffered by the Plaintiff. Rather than doing adequate testing to determine the cause of these injuries, or to rule out the design or the processes by which these Monarc and Perigee are manufactured as the cause of these injuries, the AMS Defendants chose instead to continue to market and sell the Monarc and Perigee as safe and effective.

87. AMS Defendants knew the Monarc and Perigee were unreasonably dangerous in light of their risks of failure, pain and suffering, loss of life's enjoyment, remedial surgeries and treatments in an effort to cure the conditions proximately related to the use of the Monarc and Perigee, as well as other severe and personal injuries which were permanent and lasting in nature.

88. AMS Defendants withheld material information from the medical community and the public in general, including the Plaintiff, regarding the safety and efficacy of the Monarc and Perigee.

89. AMS Defendants knew and recklessly disregarded the fact that the Monarc and Perigee can cause debilitating and potentially life altering complications with greater frequency than feasible alternative methods and/or products used to treat pelvic organ prolapse and stress urinary incontinence.

90. AMS Defendants misstated and misrepresented data and continue to misrepresent data so as to minimize the perceived risk of injuries caused by the Monarc and Perigee.

91. Notwithstanding the foregoing, the AMS Defendants continue to aggressively market the Monarc and Perigee to consumers, without disclosing the true risks associated with the Monarc and Perigee.

92. The AMS Defendants knew of the Monarc and Perigee' defective and unreasonably dangerous nature, but continued to mislead physicians and patients and to manufacture, market, distribute, and sell the Monarc and Perigee so as to maximize sales and profits at the expense of the health and safety of the public, including the Plaintiff.

93. AMS Defendants continued to conceal and/or failed to disclose to the public, including the Plaintiff, the serious complications associated with the use of the Monarc and Perigee to ensure continued and increased sales.

94. AMS Defendants' conduct as described herein shows willful misconduct, malice, fraud and oppression thereby justifying an award of punitive damages pursuant to Cal. Civ. Code § 3294(a).

95. AMS Defendants authorized and/or ratified the wrongful oppressive, fraudulent and/or malicious conduct of their employees as described herein pursuant to Cal. Civ. Code § 3294(b).

FIRST CAUSE OF ACTION

NEGLIGENCE

96. Plaintiff realleges and incorporates by reference the allegations in paragraphs 1 – 95 herein.

97. At all times herein mentioned, AMS Defendants were engaged in the business of researching, designing, manufacturing, testing, promotion, marketing, issuance of warnings, labeling, packaging, monitoring and selling the Monarc and Perigee devices at issue in this case

98. The AMS Defendants owed a duty to Plaintiff and other individuals who would use the Monarc and Perigee to use reasonable care in researching, designing, manufacturing, testing, promotion, marketing, issuance of warnings, labeling, packaging, monitoring and selling the Monarc and Perigee.

99. AMS Defendants owed to Plaintiff and the public a duty to provide accurate, reliable, and completely truthful information regarding the safety and any dangerous propensities of the Monarc manufactured, used, distributed, and/or supplied by them and to provide accurate, reliable, and completely truthful information regarding

the failure of the Monarc and Perigee to perform as intended or as an ordinary consumer would expect.

100. AMS Defendants' poor quality control and non-compliance with industry standards resulted in the non-conformance of the Monarc and Perigee implanted in Plaintiff. The implanted product did not conform to AMS's intended manufacturing, design, labeling or packaging specifications.

101. AMS Defendants' breaches of their duty of reasonable care in the design, manufacture, labeling, packaging and selling the Monarc and Perigee include:

(a) The use of polypropylene and collagen material in the Monarc and Perigee and the immune reactions that result from such material, causing adverse reactions and injuries;

(b) The design of the Monarc and Perigee to be inserted transvaginally, into and through an area of the body with high levels of bacteria that can adhere to the mesh causing immune reactions and subsequent tissue breakdown and adverse reactions and injuries;

(c) The Monarc and Perigee a large surface area of polypropylene which promotes wicking of fluids and bacteria, and is a "bacterial superhighway" providing a safe haven for bacteria;

(d) The Monarc and Perigee have very small interstices which allow bacteria to enter and hide from white blood cells and macrophages—the host defenses designed to eliminate bacteria. The bacteria also secrete an encasing biofilm, serving to further protect them from destruction by white blood cells and macrophages. In addition, some bacteria are capable of degrading polypropylene;

(e) The weave of the Monarc and Perigee mesh creates very small interstitial spaces in the mesh which are large enough for bacteria to enter but too small for the body's infection defenses (white blood cells and macrophages) to enter, allowing bacteria to easily colonize the mesh;

(f) The Monarc and Perigee mesh has a low porosity, which decreases even more when placed under mechanical stress;

(g) Biomechanical issues with the design of the Monarc and Perigee, including, but not limited to, the propensity of the Monarc and Perigee to contract or shrink inside the body, that in turn cause surrounding tissue to be inflamed, become fibrotic, and contract, resulting in injury;

(h) The propensity of the Monarc and Perigee to "creep," or to gradually elongate and deform when subject to prolonged tension inside the body;

(i) The use and design of arms and anchors in the Monarc and Perigee, which, when placed in the women, are likely to pass through contaminated spaces and that can injure major nerve routes in the pelvic region;

(j) The inelasticity of the Monarc and Perigee, causing them to be improperly mated to thedelicate and sensitive areas of the vagina and pelvis where they are implanted, and causing pain upon normal daily activities that involve movement in the pelvic region (e.g., intercourse, defecation, walking);

(k) The propensity of the Monarc and Perigee for degradation or fragmentation over time, which causes a chronic inflammatory and fibrotic reaction, and results in continuing injury over time; and

(l) The propensity of the Monarc and Perigee to contract and shrink in vivo, can result in permanent vaginal shortening or narrowing.

102. AMS Defendants further breached their duty of care in the testing and monitoring of the Monarc and Perigee devices at issue in this case, by failing to conduct adequate testing to ensure that the Monarc and Perigee were reasonably safe for implantation in the female pelvic area prior to releasing them onto the market, failing to conduct post-launch testing following adverse findings in the scientific and medical literature, and by failing to conduct post-launch testing to investigate and evaluate reports in the FDA adverse event databases for their potential significance for AMS's Vaginal Mesh Products, including the Monarc and Perigee devices at issue in this case.

103. AMS Defendants also negligently failed to warn or instruct Plaintiff and her

healthcare providers of the following:

(a) The use of polypropylene and/or collagen material in the Monarc and the immune reaction that results from such material causes adverse reactions and injuries;

(b) The design of the Monarc and Perigee to be inserted into and through an area of the body with high levels of bacteria that adhere to the mesh causing immune reactions and subsequent tissue breakdown and adverse reactions and injuries;

(c) Biomechanical issues with the design of the Monarc and Perigee, including, but not limited to, the propensity of the Monarc and Perigee to contract or shrink inside the body, that in turncause surrounding tissue to be inflamed, become fibrotic, and contract, resulting in injury;

(d) The use and design of arms and anchors in the Monarc and Perigee, which, when placed in women, are likely to pass through contaminated spaces and injure major nerve routes in the pelvic region;

(e) The propensity of the Monarc and Perigee for "creep," or to gradually elongate and deform when subject to prolonged tension inside the body;

(f) the inelasticity of the Monarc and Perigee, causing them to be improperly mated to the delicate and sensitive areas of the pelvis where they are implanted, and causing pain upon normal activities that involve movement of the pelvis;

(g) the propensity of the Monarc and Perigee for degradation or fragmentation over time, which causes a chronic inflammatory and fibrotic reaction, and results in continuing injury over time;

(h) The rate and manner of mesh erosion or extrusion;

(i) The risk of chronic inflammation resulting from the Monarc;

(j) The risk of chronic infections resulting from the Monarc;

(k) The risk of permanent vaginal scarring as a result of the Monarc;

(l) The risk of recurrent, intractable pelvic pain resulting from the Monarc;

(m) The need for corrective or revision surgery to adjust or remove the Monarc;

(n) The severity of complications that could arise as a result of implantation of the Monarc including obturator neuralgia, pudendal neuralgia, and other permanent nerve damage;

(o) Treatment of stress urinary incontinence with the Monarc is no more effective than feasible available alternatives;

(p) Treatment of stress urinary incontinence with the Monarc exposes patients to greater risk than feasible available alternatives;

(q) Treatment of stress urinary incontinence with the Monarc;

(r) Use of the Monarc puts the patient at greater risk of requiring additional surgery than feasible available alternatives;

(s) Removal of the Monarc due to complications may involve multiple surgeries and may significantly impair the patient's quality of life; and

(t) Complete removal of the Monarc may not be possible and may not result in complete resolution of the complications, including pain.

104. As a direct and proximate result of AMS Defendants' negligent design, marketing, testing, manufacturing, promotion, marketing, issuance of warnings, labeling, packaging, monitoring and selling of the Monarc and Perigee implants at issue in this case, Plaintiff sustained severe and permanent injury, experienced significant mental and physical pain and suffering, impairment of sexual function, impairment of bladder function, loss of enjoyment of life, and suffered financial or economic loss, including, but not limited to, obligations for medical services and expenses, and/or lost income, and other damages. In addition, Plaintiff has suffered an aggravation, exacerbation, and/or acceleration of her pre-existing injuries or conditions.

105. By reason of the foregoing, Plaintiff has sustained damages in an amount in excess of the jurisdiction limits of all the lower courts which would have had jurisdiction.

WHEREFORE, Plaintiff demands judgment against AMS Defendants, and each of them, individually, jointly, severally and in the alternative, and requests compensatory

damages, punitive damages, together with interest, costs of suit, attorneys' fees, and such further relief as the Court deems equitable and just.

SECOND CAUSE OF ACTION

STRICT LIABILITY – FAILURE TO WARN

106. Plaintiff realleges and incorporates by reference the allegations in paragraphs 1 – 105 herein.

107. AMS Defendants researched, developed, manufactured, inspected, labeled, distributed, marketed, promoted, sold, and otherwise released into the stream of commerce the Monarc and Perigee devices and in the course of same, directly advertised or marketed the Monarc and Perigee to healthcare professionals, consumers, and persons responsible for consumers, and therefore had a duty to warn of the risks associated with the use of the Monarc and Perigee.

108. The Monarc and Perigee implants are inherently dangerous.

109. The AMS Defendants knew or should have known of these dangers, given the generally recognized and prevailing scientific knowledge available at the time of the manufacture and distribution of Monarc and Perigee implants.

110. The AMS Defendants failed to provide adequate warning of the dangers created by the reasonably foreseeable use of these implants.

111. At the time the Monarc and Perigee implants were implanted in Plaintiff, AMS's warnings and instructions for these implants were inadequate and defective. As described in this Complaint, therewas an unreasonable risk that any Device would not perform safely and effectively for the purposes for which it was intended. AMS Defendants failed to design and/or manufacture against such dangers and failed to provide adequate warnings and instructions concerning these risks.

112. The AMS Defendants failed to properly and adequately warn and instruct Plaintiff and her healthcare providers concerning the risks of Monarc and Perigee

implants, given Plaintiff's conditions and need for that information. Neither Plaintiff nor Plaintiff's physicians, were aware of the defects and dangers of the Monarc and Perigee implants, including the frequency, severity and duration of the risks associated with these products.

113. The AMS Defendants also failed to properly and adequately warn and instruct Plaintiff and her healthcare providers concerning the inadequate research and testing of the Monarc and Perigee implants, and the complete lack of a safe, effective procedure for removal of the implants.

114. Specifically, the AMS Defendants failed to warn Plaintiff, Plaintiff's physicians and others of the following risks associated with the Monarc and Perigee implants:

(a) The use of polypropylene and/or collagen material in the Monarc and the immune reaction that results from such material causes adverse reactions and injuries;

(b) The design of the Monarc and Perigee to be inserted into and through an area of the body with high levels of bacteria that adhere to the mesh causing immune reactions and subsequent tissue breakdown and adverse reactions and injuries;

(c) Biomechanical issues with the design of the Monarc and Perigee, including, but not limited to, the propensity of the Monarc and Perigee to contract or shrink inside the body, that in turncause surrounding tissue to be inflamed, become fibrotic, and contract, resulting in injury;

(d) The use and design of arms and anchors in the Monarc and Perigee, which, when placed in women, are likely to pass through contaminated spaces and injure major nerve routes in the pelvic region;

(e) The propensity of the Monarc and Perigee for "creep," or to gradually elongate and deform when subject to prolonged tension inside the body;

(f) The inelasticity of the Monarc and Perigee, causing them to be improperly mated to the delicate and sensitive areas of the pelvis where they are implanted, and causing pain upon normal activities that involve movement of the pelvis;

(g) The propensity of the Monarc and Perigee for degradation or fragmentation over time, which causes a chronic inflammatory and fibrotic reaction, and results in continuing injury over time;

(h) The rate and manner of mesh erosion or extrusion form the Monarc and Perigee;

(i) The risk of chronic inflammation resulting from the Monarc and Perigee;

(j) The risk of chronic infections resulting from the Monarc and Perigee;

(k) The risk of permanent vaginal scarring as a result of the Monarc and Perigee;

(l) The risk of recurrent, intractable pelvic pain resulting from the Monarc and Perigee;

(m) The need for corrective or revision surgery to adjust or remove the Monarc and Perigee;

(n) The severity, duration and prevalence of complications that could arise as a result of implantation of the Monarc and Perigee including obturator neuralgia, pudendal neuralgia, and other permanent nerve damage;

(o) Treatment of stress urinary incontinence with the Monarc is no more effective than feasible available alternatives;

(p) Treatment of stress urinary incontinence with the Monarc exposes patients to greater risk than feasible available alternatives;

(q) That adequate pre-market clinical testing and research was not performed on the Monarc and Perigee;

(r) That no randomized, clinical testing on the efficacy and safety of the Monarc and Perigee implants before releasing them for public use;

(s) That the Monarc and Perigee mesh have low porosity, which decreases even more when the implants are placed under mechanical stress;

(t) The Monarc and Perigee meshes have very small interstices which allow bacteria to enter and hide from white blood cells and macrophages—the host defenses designed to eliminate bacteria. The bacteria also secrete an encasing biofilm, serving to further protect them from destruction by white blood cells and macrophages. In addition, some bacteria are capable of degrading polypropylene;

(u) The Monarc and Perigee meshes have a large surface area of polypropylene which promotes wicking of fluids and bacteria, and is a "bacterial superhighway" providing a safe haven for bacteria;

(v) The inflammatory reaction caused by the mesh causes the body to secrete acids which can cause oxidative degradation and loss of compliance or strength of the implant;

(w) Use of the Monarc and Perigee puts the patient at greater risk of requiring additional surgery than feasible available alternatives;

(x) Removal of the Monarc and Perigee due to complications may involve multiple surgeries and may significantly impair the patient's quality of life; and

(y) Complete removal of the Monarc and Perigee may not be possible and may not result in complete resolution of the complications, including pain.

115. AMS expected and intended the Monarc and Perigee implants to reach Plaintiff, their health care providers, and other consumers in the condition in which the devices were sold.

116. If Plaintiff and/or Plaintiff's physicians had been properly warned of the defects and dangers of Monarc and Perigee implants, and of the frequency, severity, and duration of the risks associated with these products, Plaintiff would not have consented to allow the Monarc and Perigee to be implanted, and Plaintiff's physician would not have implanted the Monarc and Perigee in Plaintiff.

117. As a direct and proximate result of the inadequate and defective warnings and instructions, Plaintiff has experienced significant mental and physical pain and suffering, sustained permanent injury, undergone medical treatment and will likely undergo further medical treatment and procedures, suffered financial or economic loss, including, but not limited to, obligations for medical services and expenses, and/or lost income, and other damages.

WHEREFORE, Plaintiff demands judgment against the AMS Defendants, and each of them, individually, jointly, severally and in the alternative, and requests compensatory damages, punitive damages, together with interest, costs of suit, attorneys' fees, and such further relief as the Court deems equitable and just.

THIRD CAUSE OF ACTION
STRICT LIABILITY – MANUFACTURING DEFECT

118. Plaintiff realleges and incorporates by reference the allegations in paragraphs 1 – 117 herein.

119. AMS Defendants expected and intended for their Monarc and Perigee implants to reach users such as Plaintiff in the condition in which the products were sold.

120. The implantation of the Monarc and Perigee was medically reasonable, and were the type of use that AMS Defendants intended and foresaw when they designed, manufactured and sold the implants.

121. The Monarc and Perigee implanted in Plaintiff's body were defectively manufactured. The products were not reasonably safe for their intended uses and were defective as a matter of law with respect to their manufacture in that they deviated from AMS Defendants' design and manufacturing specifications in such a manner as to pose a serious risk of serious bodily injury to Plaintiff.

122. Among other things, the AMS Defendants utilized substandard and/or

non-medical grade polypropylene and raw materials to make the Monarc and Perigee implants. Non-medical grade polypropylene contains less anti-oxidants resulting in even earlier mesh degradation and failure.

123. As a direct and proximate result of AMS Defendants' defective manufacturing of the Monarc and Perigee meshes, Plaintiff has experienced significant mental and physical pain and suffering, sustained permanent injury, undergone medical treatment and will likely undergo further medical treatment and procedures, suffered financial or economic loss, including, but not limited to, obligations for medical services and expenses, and/or lost income, and other damages

WHEREFORE, Plaintiff demands judgment against the AMS Defendants, and each of them, individually, jointly, severally and in the alternative, and requests compensatory damages, punitive damages, together with interest, costs of suit, attorneys' fees, and such further relief as the Court deems equitable and just.

FOURTH CAUSE OF ACTION

BREACH OF EXPRESS WARRANTY

124. Plaintiff realleges and incorporates by reference the allegations in paragraphs 1 – 123 herein.

125. AMS Defendants made assurances as described herein to the general public, health care professionals and Plaintiff that the Monarc and Perigee implants were safe and reasonably fit for their intended purposes.

126. Plaintiff and/or her implanting physician chose the Monarc and Perigee implants based upon AMS Defendants' warranties and representations as described herein regarding the safety and fitness of the implants.

127. Plaintiff, individually and/or by and through her physician, reasonably relied upon AMS Defendants' express warranties and guarantees that the Monarc and

Perigee implants were safe, merchantable, and reasonably fit for their intended purposes.

128. AMS Defendants breached these express warranties because the Monarc and Perigee implanted in Plaintiff were unreasonably dangerous and defective as described herein and not as Defendants had represented.

129. AMS Defendants' breach of their express warranties resulted in the implantation of unreasonably dangerous and defective products in Plaintiff's body, placing her health and safety in jeopardy.

130. As a direct and proximate result of AMS's breach of the aforementioned express warranties, Plaintiff has experienced significant mental and physical pain and suffering, has sustained permanent injury, has undergone medical treatment and will likely undergo further medical treatment and procedures, has suffered financial or economic loss, including, but not limited to, obligations for medical services and expenses, and/or lost income, and other damages.

WHEREFORE, Plaintiff demands judgment against the AMS Defendants, and each of them, individually, jointly, severally and in the alternative, and requests compensatory damages, punitive damages, together with interest, costs of suit, attorneys' fees, and such further relief as the Court deems equitable and just.

FIFTH CAUSE OF ACTION
BREACH OF IMPLIED WARRANTY

131. Plaintiff realleges and incorporates by reference the allegations in paragraphs 1 – 130 herein.

132. AMS Defendants impliedly warranted that the Monarc and Perigee were merchantable and were fit for the ordinary purposes for which they were intended.

133. When the Monarc and Perigee were implanted in Plaintiff to treat her pelvic organ prolapse and stress urinary incontinence, the Products were being used for the

ordinary purposes for which they were intended.

134. The Plaintiff, individually and/or by and through her physician, relied upon AMS' implied warranties of merchantability in consenting to have the Monarc and Perigee implanted in her.

135. AMS Defendants breached these implied warranties of merchantability because the Monarc and Perigee implanted in Plaintiff were neither merchantable nor suited for their intended uses as warranted.

136. AMS Defendants' breach of their implied warranties resulted in the implantation of unreasonably dangerous and defective products in the body Plaintiff, placing her health and safety in jeopardy.

137. As a direct and proximate result of AMS's breach of the aforementioned implied warranties, the Plaintiff experienced significant mental and physical pain and suffering, has sustained permanent injury, has undergone medical treatment and will likely undergo further medical treatment and procedures, has suffered financial or economic loss, including, but not limited to, obligations for medical services and expenses, and/or lost income, and other damages.

WHEREFORE, Plaintiff demands judgment against the AMS Defendants, and each of them, individually, jointly, severally and in the alternative, and requests compensatory damages, punitive damages, together with interest, costs of suit, attorneys' fees, and such further relief as the Court deems equitable and just.

SIXTH CAUSE OF ACTION
FRAUDULENT CONCEALMENT

138. Plaintiff realleges and incorporates by reference the allegations in paragraphs 1 – 137 herein.

139. At all times mentioned herein, the AMS Defendants, and each of them, had the duty and obligation to disclose to Plaintiff and to her physicians, the true facts

concerning the Monarc and Perigee products, that is, that said products were dangerous and defective, lacking efficacy for its purported use and lacking safety in normal use, and how likely it was for these products to cause serious consequences to users including permanent and debilitating injuries.

140. AMS Defendants owed a duty to Plaintiff to disclose and warn of the defective nature of the Monarc and Perigee because:

(a) The AMS Defendants were in a superior position to know the true quality, safety and efficacy of the AMS's Monarc and Perigee implants;

(b) The AMS Defendants knowingly made false claims about the safety and quality of the AMS's Monarc and Perigee in the documents and marketing materials Defendants provided to the FDA, physicians, and the general public; and

(c) The AMS Defendants fraudulently and affirmatively concealed the defective nature of the AMS's Monarc and Perigee from Plaintiffs.

141. AMS Defendants willfully, maliciously and oppressively concealed material facts as set forth hereinabove, from Plaintiff and her physician. prior to the time that Plaintiff was implanted with the AMS Defendants' Monarc and Perigee products. Defendants concealed these material facts with the intent to induce Plaintiff and her physician to use the AMS Defendants' Monarc and Perigee.

142. The facts concealed and/or not disclosed by AMS Defendants to Plaintiff were material factsthat a reasonable person would have considered to be important in deciding whether or not to purchase and/or use the AMS Defendants' Monarc and Perigee.

143. Plaintiff and/or her physician relied upon the concealed and/or undisclosed material facts.

144. At all times herein mentioned, neither Plaintiff nor her physician were

aware of the facts set forth above, and had they been aware of said facts, they would not have acted as they did, that is, would not reasonably relied upon said representations of safety and efficacy and utilized the AMS Defendants' Monarc and Perigee for treatment of stress urinary incontinence and pelvic organ prolapse. Further, if these material facts had been made known to Plaintiff's physician, he would have altered his prescribing behavior regarding the Monarc and Perigee implants.

145. As a direct and proximate result of AMS's concealment of the material facts above, Plaintiff was injured.

WHEREFORE, Plaintiff demands judgment against the AMS Defendants, and each of them, individually, jointly and/or severally, and requests compensatory damages, punitive damages, together with interest, costs of suit, attorneys' fees, and such further relief as the Court deems equitable and just.

SEVENTH CAUSE OF ACTION
NEGLIGENT MISREPRESENTATION

146. Plaintiff realleges and incorporates by reference the allegations in paragraphs 1 – 145 herein.

147. The AMS Defendants from the time that the Monarc and Perigee were first tested, studied, researched, first manufactured, marketed and distributed, and up to the present, made false representations, as previously set forth herein, to the Plaintiffs, their prescribing physicians and healthcare providers, the medical, scientific, pharmaceutical and healthcare communities, and the public in general, including, but not limited to, misrepresentations that the Monarc and Perigee were safe, fit, and effective for the treatment of pelvic organ prolapse and stress urinary incontinence.

148. At all times relevant hereto, AMS Defendants conducted a sales and marketing campaign to promote the sale of the Monarc and Perigee and willfully

deceive the Plaintiffs, their prescribing physicians and healthcare providers, the medical, scientific, pharmaceutical and healthcare communities, and the public in general as to the health risks and consequences of the use of the Monarc and Perigee.

149. AMS Defendants made the foregoing misrepresentations without any reasonable ground for believing them to be true. These misrepresentations were made directly by AMS Defendants, by sales representatives, detail persons and other authorized agents of said Defendants, and in publications and other written materials directed to the Plaintiffs, their prescribing physicians and healthcare providers, the medical, scientific, pharmaceutical and healthcare communities, and the public in general with the intention of inducing reliance and the purchase and implantation of the Monarc and Perigee.

150. The foregoing representations by the AMS Defendants were in fact false in that the Monarc and Perigee products are not, and at all relevant times alleged herein, were not safe, fit, and effective for the treatment of pelvic organ prolapse, stress urinary incontinence and/or rectocele, the use of the Monarc and Perigee is hazardous to health, and the Monarc and Perigee have a significant propensity to cause serious injuries to users including, but not limited to, the injuries suffered as described herein. The foregoing misrepresentations by the AMS Defendants were made with the intention of inducing reliance and inducing the purchase and implantation of the Monarc and Perigee.

151. In reliance on the misrepresentations by the AMS Defendants, Plaintiffs and their prescribing physicians and healthcare providers were induced to purchase use the Monarc and Perigee. If they had known of the true facts and the facts concealed by the AMS Defendants, they would not have used the Monarc and Perigee, and their reliance upon these misrepresentations was justified because such misrepresentations were made and conducted by individuals and entities that were in superior position of knowledge and knew the true facts.

152. As a proximate result of the misrepresentations of material facts set forth above, Plaintiff experienced significant mental and physical pain and suffering, has sustained permanent injury, has undergone medical treatment and will likely undergo further medical treatment and procedures, has suffered financial or economic loss, including, but not limited to, obligations for medical services and expenses, and/or lost income, and other damages.

WHEREFORE, Plaintiff demands judgment against the AMS Defendants, and each of them, individually, jointly and/or severally, and requests compensatory damages, together with interest, costs of suit, attorneys' fees, and such further relief as the Court deems equitable and just.

PRAYER FOR RELIEF

WHEREFORE, Plaintiff prays for judgment against the AMS Defendants, and each of them, as follows:

1. For past, present and future general damages, including, but not limited to, pain and suffering for severe and permanent injuries sustained by Plaintiff;
2. For past and future medical and incidental expenses;
3. For past and future lost income and/or loss of earning capacity;
4. For punitive and exemplary damages in an amount to be determined at trial;
5. For costs; and

6. For such other and further relief as the Court may deem just and proper, including costs and prejudgment interest as provided by C.C.P. section 998, C.C.P. section 1032, and related provisions of law.

JURY DEMAND

Plaintiff demands a trial by jury on all issues that may be tried by a jury.

Respectfully submitted,

/s/ Chris W. Cantrell

Chris W. Cantrell (SBN 290874)
DOYLE APC
550 West B Street, Fourth Floor
San Diego, CA 92101
Telephone: (619) 736-0000
Facsimile: (619) 736-1111

William J. Doyle (SBN 188 069)
DOYLE APC
550 West B Street, Fourth Floor
San Diego, CA 92101
Telephone: (619) 736-0000
Facsimile: (619) 736-1111